

GDUFA Facility Arrears List (06/18/2013)

The following facilities have not satisfied their annual facility fee as required under GDUFA. The facility fee, incurred pursuant to § 744B(a)(4)(A)(i), was due no later than March 04, 2013. Failure to timely submit the annual facility payment means that the Food and Drug Administration (FDA) will not be able to receive new ANDAs or PASs referencing these facilities within the meaning of § 505(j)(5)(A) until the outstanding fee is paid. The FDA will also not be able to receive applications submitted by the owners, or affiliates of the owners, of these facilities.

If your records indicate that a facility fee was previously submitted, please contact AskGDUFA@fda.hhs.gov and provide the following information: Facility name, DUNS, FEI number, User Fee Payment I.D. Number (PIN), and the payment method, date and amount. Additionally, if you feel that your facility is not subject to GDUFA fees, please contact AskGDUFA@fda.hhs.gov and provide a brief explanation for your reasoning. The agency will review your explanation and respond to it promptly.

We encourage you to seek verification from your business partners that all applicable fee(s) have been received in full by the Agency in order to minimize the risk that a receipt of an application will be jeopardized.

FACILITY NAME	FEI NUMBER	GDUFA OPERATION
5N Plus Lübeck GmbH	3002807159	API
Acino AG	3007515173	FDF
Air Liquide Electronics U.S. LP	1000122308	API
Akzo Nobel Salt A/S	3005406532	API
Allergan, Inc. (Waco)	1643525	FDF
American Antibiotics, Inc.	3005425963	FDF
American Peptide Company	3000718309	API
Antibioticos, SA	3002806372	API
Bioindustria L.I.M. S.p.A. Novi Ligure Plant	3002717526	FDF
Biovectra Inc	3003961730	API
Blenheim Pharmacal, Inc.	3004765103	FDF
BSP Pharmaceuticals Srl	3007255826	FDF
Calaire Chimie SAS	3002806640	API
Cambridge Major Laboratories Europe B.V.	3004153149	API
CF Pharma Ltd.	3004743234	API
China Resources Saike Pharmaceutical Co., Ltd.	3002806597	FDF
Cobrek Pharmaceuticals, Inc.	3003461362	API
Colgate Oral Pharmaceuticals, Inc.	1000117969	FDF
Contract Coating Inc.	2245363	FDF
Croda Europe Ltd.	3004322377	API

Daiichi Sankyo Bethlehem	3003673570	FDF
DPT Lakewood, LLC	2242829	FDF
Encube Ethicals Pvt. Ltd	3005669319	FDF
Exemplar Pharmaceuticals LLC	3006571100	FDF
Explora Laboratories SA	3006254830	API
FineTech Pharmaceutical Ltd.	3003971812	API
Fujimoto Chemicals Co. Ltd.	3002806358	API
Golden State Medical Supply	3006458969	FDF
Guardian Drug Company	2245306	FDF
Hainan Hailing Chemipharma Corporation Limited	3006643956	FDF
Hubei Haosun Pharmaceutical Co., Ltd.	3005178749	API
Intellipharmaeueutics Corp.	3006370451	FDF
Korea United Pharm Inc.	3006045458	API
Laboratorios Senosiain, S.A. de C.V.	3004413356	FDF
Lehigh Valley Technologies, Inc.	3003851100	FDF
LOBA Feinchemie Gmbh	3002807485	API
Marck Biosciences Limited	3006257565	FDF
Megafine Pharma (P) Limited	3006688078	API
MicroTest Laboratories, Inc.	1220785	FDF
Nantong Jinghua Pharmaceutical	3003735909	API
Novartis Pharma Stein AG	3002653483	FDF
Purdue GMP Center LLC	3005071685	FDF
PureTek Corporation	1000125324	FDF
Rainbow Gold Products, Inc.	3002784388	FDF
RPG Life Sciences Limited	3003269328	API
Second Pharma Co., Ltd.	3004836637	API
Unimark Remedies Limited	3005202703	API
Vital Laboratories Private Limited	3007474872	API